PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Imlygic Prior Authorization Policy
- Imlygic® (talimogene laherparepvec intralesional injection – Amgen)

REVIEW DATE: 04/06/2022

OVERVIEW

Imlygic is an oncolytic viral therapy indicated for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with **melanoma** recurrent after initial surgery.[1] It is a limitation of use that Imlygic has not been shown to improve overall survival or have an effect on visceral metastases. Imlygic should be continued for at least 6 months, unless other treatment is required or there are no injectable lesions to treat and may also be reinitiated if new unresectable cutaneous, subcutaneous, or nodal lesions appear following a complete response. In the pivotal trial, adults with unresectable stage III (30%) or stage IV (70%) melanoma were treated for at least 6 months, or until no remaining injectable lesions. During the initial 6 months of the trial, treatment continued despite increased size or number of lesions. Following 6 months of treatment, patients could continue Imlygic until clinically relevant disease progression (i.e., disease progression associated with a decline in performance status and/or alternative therapy was needed, according to the prescriber). For storage beyond 1 week, Imlygic requires specialized conditions (-130° to -94° F). Personal protective equipment (including a gown/laboratory coat, safety glasses or face shield, and gloves) while preparing or administering, and procedures for accidental exposure to Imlygic should be followed. Safety and efficacy have not been established in patients < 18 years of age.

Clinical Efficacy

In the pivotal trial, the initial dose of Imlygic was administered at 10^6 plaque forming units (PFU)/mL (to seroconvert herpes simplex virus-seronegative patients). Subsequent doses were 10^8 PFU/mL administered 3 weeks after the first dose, then every 2 weeks. Total volume of Imlygic was up to 4.0 mL per treatment session. It may not be possible to inject all lesions at each treatment visit or over the full course of treatment. Previously injected and/or uninjected lesions may be injected at subsequent treatment visits. Continue treatment for at least 6 months unless other treatment is required or until there are no injectable lesions to treat. Imlygic may be reinitiated if new unresectable cutaneous, subcutaneous, or nodal lesions appear after a complete response.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for melanoma (version 2.2022 – January 26, 2022) list Imlygic as an option in multiple treatment situations, including for Stage III melanoma; for recurrent disease (including nodal recurrence); for disseminated metastatic disease; and in combination with Yervoy (ipilimumab injection), for metastatic or unresectable disease following disease progression or maximal clinical benefit from BRAF targeted therapy.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Imlygic. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Imlygic as well as the monitoring required for adverse events and long-term efficacy, approval requires Imlygic to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

FDA-Approved Indication

1. **Melanoma.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy (This includes reinitiation in patients with new lesions following a complete response). Approve for 6 months if the patient meets ALL of the following (i, ii, and iii):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Imlygic will be directly injected into advanced, metastatic, recurrent, or unresectable cutaneous, subcutaneous, or nodal lesions; AND
     - **iii.** Imlygic will be administered by or under the supervision of an oncologist, dermatologist, or surgeon.
   - **B)** Patient is Currently Receiving Imlygic. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
     - **i.** Patient has remaining injectable lesions for treatment; AND
     - **ii.** According to the prescriber, the patient has not experienced clinically relevant disease progression (e.g., disease progression associated with a decline in performance status and/or alternative therapy was needed); AND
     - **iii.** Imlygic will be administered by or under the supervision of an oncologist, dermatologist, or surgeon.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Imlygic is not recommended in the following situations:

1. **Concurrent Use with Anti-Herpetic Viral Agents.** Imlygic is a genetically modified, live, attenuated herpes simplex virus-1 that is sensitive to acyclovir. Anti-herpetic viral agents (e.g., acyclovir, valacyclovir, famciclovir) may interfere with efficacy.

2. **Immunocompromised Patients.** Imlygic is contraindicated in patients who are immunocompromised, including those with a of primary or acquired immunodeficient states, leukemia, lymphoma, acquired immunodeficiency syndrome, or other clinical manifestations of infection with human immunodeficiency viruses, and those on immunosuppressive therapy.

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Imlygic intralesional injection [prescribing information]. Thousand Oaks, CA: BioVex/Amgen; December 2021.
2. Dharmadhikari N, Mehnert JM, Kaufman HL. Oncolytic virus immunotherapy for melanoma. *Curr Treat Options Oncol*. 2015;16(3):326.
3. Moehler M, Goepfert K, Heinrich B, et al. Oncolytic virotherapy as emerging immunotherapeutic modality: potential of parvovirus h-1. *Front Oncol*. 2014;4:92.
4. The NCCN Cutaneous Melanoma Clinical Practice Guidelines in Oncology (version 2.2022 – January 26, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 1, 2022.